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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/890,490	07/09/97	ANTHONY FENN R	F3141(V)

MK

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PATENT DEPARTMENT
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EXAMINER	
NESSLER, C	
ART UNIT	**PAPER NUMBER**
1761	25

DATE MAILED: 08/29/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/890,490	Applicant(s) Fenn et al
	Examiner Cynthia L. Nessler	Group Art Unit 1761

☒ Responsive to communication(s) filed on *Jun 8, 2000* .

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *5 and 6* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *5 and 6* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Clemmings et al or Warren et al in view of WO 92/22581, applicants' admission, and the Griffith et al article "Antifreeze Proteins and Their Use in Frozen Foods".

Either Clemmings et al or Warren et al disclose the use of antifreeze peptides in frozen confectionary products and mixes such as ice cream. The claims differ in the recitation of the aspect ratio. As admitted by the applicants in the first paragraph of page 2 of the specification, antifreeze peptides are known for their ability to influence the shape of ice crystals (according to WO 92/22581). The aspect ratio is a measurement of the shape of a particle, such as a crystal (typically a length ratio of the major to minor axis of the crystal). The aspect ratio (shape) of the crystals is therefore considered to be a result effective variable, dependent upon, for example, the desired texture and mouthfeel of the final product, absent a showing of unexpected results. It would have been obvious to utilize the antifreeze peptides of either Clemmings et al or Warren et al in the frozen confectionary products of either primary reference to influence the shape of the ice crystals formed in order to provide a desired aspect ratio and a desired texture.

Note in lines 11-22 of page 21 of WO 92/22581 that low concentrations of antifreeze proteins preferentially inhibit the a-axis growth, while at high concentrations, the crystals grow predominantly along the c-axis to form hexagonal bipyrimids. Therefore, WO 92/22581 teaches that the concentration of the antifreeze proteins influences the shape (i.e., the aspect ratio) of the ice crystals formed. Also note that WO 92/22581 teaches the application of the invention to ice cream and other frozen foods in lines 20-30 of page 30. It therefore would have been obvious to

alter the conditions by controlling the concentration antifreeze proteins of either Clemmings et al or Warren et al to influence the shape of the ice crystals as taught by WO 92/22581.

While Clemmings et al teach particle sizes averaging 27 microns in line 56 of column 4, the Griffiths et al article teach, on page 391 in the first paragraph of the section entitled "Addition of Antifreeze Proteins Directly to Foods", that ice cream can be frozen with higher concentrations of antifreeze proteins to minimize the size of the ice crystals. Therefore the ice crystal size is a result effective variable, dependent upon, for example, the antifreeze protein concentration and the desired texture in the end product. See also the penultimate paragraph of page 387 of the Griffiths et al article, teaching that the inhibition of ice recrystallization (i.e., control of the ice crystal size) can be an important factor in determining the texture of ice cream. Griffiths also teaches. in the "Conclusions" section found on page 393, that the concentrations and types of AFP's in frozen foods are selected, depending upon, for example, the range of temperatures used in processing, or the desired texture (at high concentrations, spicular ice formation may cause cellular injury; at low concentrations, the texture and flavor of frozen foods is maintained). Therefore, the type and concentration of the AFP's are result effective variables which influence the shape (i.e., aspect ratio) of the crystals as well as the texture of the final ice cream product. Therefore, the ice crystal size as well as the type and concentration of antifreeze proteins in the frozen confection is a result effective variable for the reasons discussed above. Note in any event that Clemmings teaches concentrations of antifreeze proteins which overlap the recited range in liens 47-50 of column 2.

Regarding the recitation of the type of antifreeze protein (Type III HPLC 12), while Clemmings et al teach that Type I antifreeze proteins are preferred, Clemmings teaches that the other types (II and III) are also effective. Also, the Griffiths et al article teaches the use of not only Type III but also that the type of antifreeze protein is selected depending upon the range of temperatures used in processing or the desired texture in the end product (see the discussion immediately above). Therefore Griffiths teaches that the selection of the type is a result effective variable.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (f) he did not himself invent the subject matter sought to be patented.

Claims 5 and 6 are rejected under 35 U.S.C. 102(f) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over WO 97/02343. Claims 5 and 6 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. WO 97/02343, filed by an entirely different inventive entity (no common inventors listed) teach the preferred embodiment of the recited antifreeze protein type in ice cream on page 12. The recited properties such as aspect ratio and particle size are inherent, or if not fully inherent, are result effective variables dependent upon the desired texture of the final ice cream product absent a showing of unexpected results as discussed above.

Claims 5 and 6 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Tripp et al.

Tripp et al teach the recited antifreeze protein in ice cream in Example 4 (columns 16-18). The recited properties such as aspect ratio and particle size are inherent, or if not fully inherent, are result effective variables dependent upon the desired texture of the final ice cream product absent a showing of unexpected results as discussed above.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Arai et al teach frozen foods containing antifreeze proteins. Arai teaches concentrations within the presently recited range in line 20 of column 3. Note particularly lines 23-26 of column 3 of Arai, which teach "an amount of the antifreezing agent varies depending upon the desired storage temperature, kinds of product to be frozen, a rate of cooling, and the like". Therefore, Arai teaches that the amount of antifreezing agent present is a result effective variable.

Lee teach, in lines 37-41 of column 7, that the amount of material to be added to assist in ice nucleation according to the present invention will depend upon the nature of the material used and in particular on the temperature at which it will induce nucleation in supercooled water. Ice nucleating proteins are disclosed.

Fletcher et al teach that the number of fish antifreeze-expressing microorganisms added to the food product will depend on the properties of the microorganisms and of the food.

Arbuckle, "Ice Cream", third edition, on page 323, expressly teaches that the texture of ice cream is dependent upon variables such as the shape of the ice crystals (see the first and second paragraphs under the heading "Body and Texture Defects"). In the paragraph bridging pages 325 and 326, Arbuckle teaches that the texture also depends on the size of the crystals. In the first two lines of page 330, Arbuckle teaches that rate of freezing and hardening affect texture; and that fast freezing produces small ice crystals.

Perry's Chemical Engineering Handbook, sixth edition, teaches that the "aspect ratio" is used to describe the shape of a particle, and that the particle shape can be related to functional properties of the particles.

Gordon et al, in column 11, lines 10-40, teaches textbook information regarding the aspect ratio measurement. Lines 47-48 of column 3 of Nordhauser et al teach that the aspect ratio has historically been used to demonstrate particle shape.

Applicant's arguments filed June 8, 2000 have been fully considered but they are not persuasive.

The applicants argue that all known products containing ice crystals have an aspect ratio of less than 1.9. The applicants also argue that they have provided evidence that shows that other AFP's can influence the shape of the ice crystal, but the aspect ratio achieved is less than 1.9. However, first, the only comparison provided by the applicants is a comparison with Clemmings

using Type I AFP. Both Clemmings and the Griffith article also teach Type III AFP; therefore, a proper comparison has not been made.

Furthermore, as discussed in the Advisory Action (Paper No. 20) dated October 8, 1999, the Cheeney declaration shows that the Clemmings product of Example 1 does not inherently have the recited aspect ratio. But the declaration does not show why it would not have been obvious to adjust the aspect ratio to a desired value, since the aspect ratio, as well as the particle sizes, are result effective variables as discussed above. The Cheeney declaration does not show why the recited aspect ratio or particle size is unexpected. In fact, the Griffiths article teaches that ice cream can be frozen with higher concentrations of antifreeze proteins to minimize the size of the ice crystals. Therefore the ice crystal size is a result effective variable, dependent upon, for example, the antifreeze protein concentration and the desired texture in the end product. Griffiths also teaches. in the "Conclusions" section found on page 393, that the concentrations and types of AFP's in frozen foods are selected, depending upon, for example, the range of temperatures used in processing, or the desired texture (at high concentrations, spicular ice formation may cause cellular injury; at low concentrations, the texture and flavor of frozen foods is maintained). Therefore, the type and concentration of the AFP's are result effective variables which influence the shape (i.e., aspect ratio) of the crystals as well as the texture of the final ice cream product. The ice crystal size as well as the type and concentration of antifreeze proteins in the frozen confection is a result effective variable for the reasons discussed above. Note in any event that Clemmings teaches concentrations of antifreeze proteins which overlap the recited range in lines

47-50 of column 2. Also note that example 1 of Clemmings does not represent the entire antifreeze protein concentration range taught in lines 48-50 of column 2, nor have the applicants compared example 2 of Clemmings, teaching the smaller particle size. Therefore while Example 1 of Clemmings does not inherently produce the properties recited, applicants have provided no quantified evidence of unexpected results, including why the choice of antifreeze protein type, the recited particle size, or the aspect ratio is unexpected. The use of smaller particle sizes to obtain a smoother texture would not be unexpected, for example. Griffiths teaches that the aspect ratio and particle size depend on the type and concentration of the antifreeze proteins.

The Sztehlo declaration does not provide a proper comparison because the amounts of ingredients, especially antifreeze protein, do not match those of Example II of the specification, for comparison of Warren and the present specification.

The Sidebottom declaration provides no data regarding the ice crystal sizes obtained from the various proteins isolated. The sole indication is the conclusory statement in paragraph 6 that only a protein having a molecular weight of 32 kDa provides an ice crystal size number average of less than 20 um when tested according to Example V. The data was not presented. Nor were data presented for proteins of molecular weights other than 32 kDa. Therefore there is no way to make a comparison, and the declaration was not found persuasive.

The applicants have argued that the Clemmings et al and Warren et al references do not recognize that the textural properties of an AFP containing frozen food are a function of the aspect ratio of its ice-crystals. However, first, Clemmings explicitly discloses that the smaller ice

crystals in the anti-freeze protein treated yogurt resulted in a smoother texture and mouthfeel than that in the yogurt without AFP (see lines 58-60 of column 4). Even more importantly, it is textbook knowledge that the shape of the ice crystals affects the texture of the frozen confection (see, e.g., page 323 of Arbuckle, "Ice Cream", third edition, discussed immediately above). Furthermore, the aspect ratio is a standard measurement which defines the shape of the particles, and has historically been used to demonstrate particle shape (see, e.g., Perry's Chemical Engineering Handbook, discussed above). Therefore, that the textural properties of a frozen confection are a function of the aspect ratio (i.e., shape) of the ice crystals, is textbook knowledge.

The applicants have argued that Clemmings or Warren do not teach the presently recited aspect ratio. However, the shape (aspect ratio) of the crystals is a result effective variable, dependent upon, for example, the desired texture and mouthfeel of the food, absent a showing of unexpected results. To date, evidence of unexpected results has not been submitted.

Attention is invited to *In re Levin*, 84 USPQ 232 (1949) and the cases cited therein, which are considered relevant to the fact situation of the instant case, and wherein the Court stated on page 234 as follows:

> This court has taken the position that new recipes or formulas for cooking food which involve the addition or elimination of common ingredients, or for treating them in ways which differ from the former practice, do not amount to invention, merely because it is not disclosed that, in the constantly developing art of preparing food, no one else ever did the particular thing upon which the applicant asserts his right to a patent. In all such cases, there is nothing patentable unless the applicant by a proper showing further establishes a coaction or cooperative relationship between the selected ingredients which produces a new, unexpected, and useful function. *In re*

Benjamin D. White, 17 CCPA (Patents) 956, 39 F.2d 974, 5 USPQ 267; *In re Mason et al*, 33 CCPA (Patents) 1144, 156 F.2d 189, 70 USPQ 221.

In the absence of unexpected results, it is not seen how the claimed invention differs from the teachings of the prior art. Applicant's claims are drawn to a combination of known components which produces expected results. See *In re Kerkhoven*, 205 USPQ 1069 and *In re Gershon*, 152 USPQ 602.

The applicants argue that Clemmings is aimed at the minimization of the crystal size and not the crystal shape. WO 92/22581, however, teaches that the presence of antifreeze proteins inherently influences the shape. And again, that the textural properties of a frozen confection are a function of the aspect ratio (i.e., shape) of the ice crystals, is textbook knowledge. The aspect ratio is purely a measurement of a physical phenomenon (i.e., the applicants did not invent the aspect ratio itself).

The statement in lines 34-37 of page 5 of the present specification that "applicants believe that it is well within the ability of the skilled person to choose those conditions such that the aspect ratio of the ice crystals falls within the desired range" is also noted.

The applicants have argued that prior to the present invention, the use of antifreeze peptides in frozen foods was not known in commercial circles. However, the references clearly disclose the presence of antifreeze peptides in frozen foods/ice cream, as well as their use to influence the shape of ice crystals. Since the aspect ratio measures this property, the choice of a

desired aspect ratio to suit the desired shape of the ice crystals and the desired texture or mouthfeel of the final product is considered to have been obvious absent a showing of unexpected results.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any concerning this communication or earlier communications from the examiner should be directed to Cynthia L. Nessler whose telephone number is (703) 308-3843.

Cynthia L. Nessler

cn

August 28, 2000

CYNTHIA L. NESSLER
PRIMARY EXAMINER
GROUP 1300